

121



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,640	12/02/2003	Eric Cossement	2003_1709	2005
513 7590 04/07/2004 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER BERNHARDT, EMILY B	
			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/724,640

Applicant(s)

COSSEMENT ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 9-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/207,096.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/2/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1624

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baltes (US'358) and applicants' own admission (see p.7 of the specification).

Baltes teaches the racemic forms of instant compounds. See amide derivative in col.5 lines 56-60 . The reference teaches the amide derivative for uses associated with antihistaminic activity. Applicants' admission as disclosed in the specification is also relied on for showing that preparation of instant isomers is within the skill of the art as discussed on p.2 and p.7-8 . While the patent does not expressly teach resolution of the racemates into the respective optical isomers, the instant levo and dextro isomers, recited with a purity limitation, are held as obvious variants over the racemates taught to be old for uses claimed herein in view of their very close

Art Unit: 1624

structural similarity and the fact that one skilled in the art would recognize the existence of such isomers and be able to prepare such employing known procedures such as the one admitted to be old in the specification . Note In re Adamson 125 USPQ 233. There is additional case law regarding the patenting of a component of an old mixture. See Pfizer v. International Rectifier 190 USPQ 273; Eli Lilly v. Generix 174 USPQ 65. In another case In re Volwiler 46 USPQ 137 the requirement for patentability of an isolated highly pure component from a mixture was deemed to be possession of unexpectedly different properties than that of the mixture. Also see In re May 197 USPQ 601 in which the non-addictive nature of the appealed isomer(s) was not a property known for related compounds but of long felt need in the art and so this combined with analgesic activity was deemed an unexpected result. See also Sterling Drug v. Watson 108 USPQ 37. Thus it would have been obvious to one skilled in the art at the time the invention was made to expect instant isomers to also possess the uses taught or admitted to be old in the prior art in view of the well known knowledge of stereoisomerism and the expectation that at least one of a pair is expected to retain the activity of the racemic form as discussed above.

Art Unit: 1624

Commonly assigned US'942 is made of record. Claims allowed are distinct from that claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600